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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,796	03/13/2000	DOMINIQUE BRASSART	P99:2625	1391

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EXAMINER

AFREMOVA, VERA

ART UNIT PAPER NUMBER

1651

DATE MAILED: 05/30/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/445,796

Applicant(s)

Brassart et al.

Examiner

Vera Afremova

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 7, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11-26 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on Jan 8, 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: \_\_\_\_\_

Art Unit: 1651

## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on 2/07/2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/445,796 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 11-23 as amended and new claims 24-26 [Paper No. 18 filed 2/07/2002] are pending and under examination in the instant office action.

Claims 1-10 were canceled by applicants in the Paper No. 10 filed 6/04/2001.

### ***Deposit***

The deposit requirement for *Lactobacillus johnsonii* CNCM I-1225 has been met in the Paper No. 10 filed 6/04/2001.

### ***Claim Rejections - 35 U.S.C. § 112***

Claims 11-15, 20 and 26 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as explained in the prior office action and for the reasons below.

Claim 11 is rendered indefinite by the phrase "treatment or prophylaxis of treating mineral deficiencies in a mammal" because it is confusing what is "treatment" of "treating mineral deficiencies in mammal" and/or "prophylaxis of treating mineral deficiencies in a mammal" as claimed.

Art Unit: 1651

Claims 14 and 26 are rendered indefinite by recitation of "cfu/ml" wherein amounts of the composition are expressed by volume however the nature of the claimed nutritional composition is not specified. Is it solid or liquid, for example? Thus, a reference to a volume lacks an antecedent basis. Further, the amounts which are claimed do not indicate a link between the CFU amounts in the nutritional composition and the amounts of the whole composition intended for enteral administration. Thus, claims fail to point out the subject matter which applicant regards as the invention such as protocols for preventing and/or for treating mineral deficiencies in mammal or protocols for increasing absorption of mineral from diets by mammals as the result of enteral administration of a composition comprising one or more *Lactobacillus*. Whether are the same or different amounts of the composition intended for each claimed method comprising step of enteral administration, for example?

Claims 15 and 20 are indefinite because it is not particularly clear as claimed whether or not the claimed minerals are intended to be included in the nutritional compositions in the method of administration.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 1651

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-13, 15-23 as amended and new claims 24 and 25 are rejected under 35

U.S.C. 102(b) as being anticipated by US 5,578,302 [B].

Claims 11-23 as amended and new claims 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,494,664 [A].

The claims are directed to methods for treatment or prophylaxis of mineral deficiencies in a mammal or for improving absorption of minerals from the diet wherein the methods comprise step of enterally administering to a mammal a nutritional composition comprising one or more *Lactobacillus* bacteria. Some claims are further drawn to the use of *Lactobacillus* sp. CNCM I-1225 in the method of administration of the nutritional composition. Some claims are further drawn to the use of milk products and/or milk hydrolysates in the nutritional composition in the method of administration. Some claims (14 and 26) are further drawn to the use of lactobacteria in amounts  $10^7$  to  $10^{11}$  CFU/ml in the method of administration of the nutritional composition.

The cited US 5,578,302 [B] and US 5,494,664 [A] are relied upon as explained in the prior office action and repeated herein.

US 5,578,302 [B] (abstract) teaches a method for improving mammal health wherein the method comprises enterally administering to a mammal a nutritional composition which contains bacteria belonging to the genus *Lactobacillus* including particular strain *Lactobacillus johnsonii*

Art Unit: 1651

(*acidophilus*) CNCM I-1225 (col. 2, line 13) in nutritional composition in a form of yogurt or milk-based powdered formulations (col.1, lines 43-44).

US 5,494,664 [A] (col. 1, line 43-60 and col. 2, line 14) teaches a method for improving mammal health wherein the method comprises enterally administering to a mammal a nutritional composition which contains lactobacteria and/or bifidobacteria including *Lactobacillus acidophilus (johnsonii)* CNCM I-1225 in amounts  $10^7$  to  $10^8$  CFU/ml in nutritional composition in a form of yogurt or other milk-based product.

The cited patents are considered to anticipate the claimed invention because the methods of the cited patents are one active step methods which comprise one step of enterally administering an identical composition comprising one or more bacteria belonging to the genus of *Lactobacillus* or one or more bacteria belonging to the strain CNCM I-1225 belonging to the species of *Lactobacillus johnsonii* (priority identified as *acidophilus*) to identical an identical mammalian patient as the claimed method. Consequently, the results of practicing identical protocols of administering are reasonably expected to be identical as intended and as claimed. Both methods of the cited patents comprise the use of compositions with milk ingredients as well as ingredients of whole cell preparations derived from one or more *Lactobacillus* bacteria as the claimed method, and, thus, administration of identical compositions with identical components as claimed are reasonably expected to inherently provide mammalian patients with benefits related to treatment or prophylaxis of mineral deficiencies or for improving absorption of minerals from the diet as intended for the claimed method. Moreover, the method of US

Art Unit: 1651

5,494,664 [A] teaches the use of nutritional compositions with that same amounts of the same bacterial strain CNCM I-1225 as the claimed method. Thus, identical benefits are inherent to the administration. Therefore, the methods are identical as disclosed and as claimed.

***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-23 as amended and new claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,578,302 [B] or US 5,494,664 [A] taken with Yaeshima [IDS-3-AR], Yoshida [U] and Sellars [U-19].

The claims are directed to methods for treatment or prophylaxis of mineral deficiencies in a mammal or for improving absorption of minerals from the diet wherein the methods comprise step of enterally administering to a mammal a nutritional composition comprising one or more bacteria belonging to the genus of *Lactobacillus* bacteria. Some claims are further drawn to the use of particular strain CNCM I-1225 belonging to *Lactobacillus johnsonii* (priorly identified as *acidophilus*) in the method of administration of the nutritional composition. Some claims are further drawn to the use of milk products and/or milk hydrolysates in the nutritional composition

Art Unit: 1651

in the method of administration. Some claims are further drawn to the use of bacteria in amounts  $10^7$  to  $10^{11}$  CFU/ml in the method of administration of the nutritional composition.

The cited patents US 5,578,302 [B] or US 5,494,664 [A] are relied upon as explained above for the disclosure of the methods of administering nutritional compositions comprising bacteria belonging to the genus of *Lactobacillus* including particular strain CNCM I-1225 *Lactobacillus johnsonii* (priority identified as *acidophilus*). The cited methods clearly teach health improvement of mammals as the result of administering compositions with various lactobacteria including bacteria that which are presently claimed. However the cited patents are silent with regard to particular effects as claimed such as treatment or prophylaxis of mineral deficiencies in a mammal or for improving absorption of minerals from the diet.

However, the references by Yaeshima [IDS-3-AR] and Yoshida [U] teaches method for treatment and/or improving mineral absorption by administering lactobacteria or bifidobacteria to mammals. For example: the cited references by Yaeshima [IDS-3-AR] (page 41) and Yoshida [U] (abstract) disclose a method for increasing absorption of minerals from the diet wherein the method comprises enterally administering to a mammal a nutritional composition with lactobacteria or bifidobacteria including representatives of the genus *Bifidobacterium* alone or with additional products such as dietary fibers (oligosaccharides or lactulose ) and minerals (calcium, magnesium, etc.).

Further, the reference by Sellars [U-19] teaches that the acidophilus products comprising representatives of bacterial genera *Lactobacillus* and/or *Bifidobacterium* or including



Art Unit: 1651

representatives of bacterial species *Lactobacillus acidophilus* (see tables I-III at pages 84-86) are known to exhibit health promoting properties associated with establishment of an acidophilus microflora in mammals including the health benefit such as increasing rate of mineral absorption or increasing bioavailability of minerals (page 100, par. 3). The references also teaches that the consumption of fermented dairy products containing lactobacteria increases mineral absorption from diets depending on age and state of various patients (page 102, par. 2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use bacteria belonging to the genus *Lactobacillus* or to the strain CNCM I-1225, which is *Lactobacillus johnsonii* (priorly identified as *acidophilus*), in the method of administering to mammals with a reasonable expectation of success in treating mineral deficiencies in mammals and/or improving absorption of minerals from diets because consumption of products comprising various lactobacteria including bacteria belonging to *Lactobacillus* and/or *Bifidobacterium* or including bacteria belonging to the species of *Lactobacillus acidophilus* been taught and suggested in the prior art for promoting mammalian health including health benefits such as increasing mineral absorption from diets. Further, it is considered to be within the skills of an ordinary practitioner in the field to adjust amounts and components of the nutritional compositions intended for treatment or prophylaxis of mineral deficiencies or for improving absorption of minerals from diets depending on patient age, life style and/or general state of health. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Art Unit: 1651

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

Art Unit 1651

May 29, 2002.

  
**IRENE MARX**  
**PRIMARY EXAMINER**